UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

TAMARA J. TOWNSEND, Plaintiff, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	Case No. 2:20-cv-01984-ART-DJA ORDER

Plaintiff Tamara Townsend brings this action for injuries sustained following surgical implantation of a pelvic mesh product, the TVT-Abbrevo, manufactured by Defendants. This case is one of many that were joined in multidistrict litigation ("MDL") in the Southern District of West Virginia. (MDL No. 2327.) Before the Court are: (1) Defendants' motion for summary judgment (ECF No. 111); and (2) six motions brought by Defendants to limit the testimony or opinions of Plaintiff's experts, namely: (i) Dr. Paul J. Michaels (ECF No. 112); (ii) Dr. Med. Uwe Klinge (ECF No. 113); (iii) Dr. Jeremy Blaivas (ECF No. 114); (iv) Dr. Bruce Rosenzweig (ECF No. 115); (v) John Cary, MA (ECF No. 116); and (vi) Scott Guelcher, Ph.D. (ECF No. 117).

For the reasons set forth in this order, the Court denies Defendants' motion for summary judgment as to Plaintiff's failure to warn strict liability claim, grants summary judgment as to Plaintiff's fraud and negligence-based claims as duplicative of the strict liability claims, and grants summary judgment as to Plaintiff's defective product and unjust enrichment claims by virtue of Plaintiff's consent to withdrawal of those claims. (ECF No. 111.) The Court further: (1) denies Defendants' motions to limit the testimony of Dr. Michaels (ECF No. 112) and Mr. Cary (ECF No. 116); (2) denies as moot Defendants' motion to limit the testimony of Dr. Blaivas (ECF No. 114) due to Plaintiff's withdrawal of Dr. Blaivas

as an expert; and (3) grants in part and denies in part Defendants' motions to limit the testimony of Dr. Klinge (ECF No. 113), Dr. Rosenzweig (ECF No. 115), and Dr. Guelcher (ECF No. 117).

I. BACKGROUND

Plaintiff received a TVT-Abbrevo implant on January 17, 2012, at St. Rose Dominican Hospital in Henderson, Nevada. (ECF No. 111-1 at 5.) Dr. Paula Schwartz performed the implantation surgery and Dr. James Oliver assisted. (ECF No. 111-3 at 7:20–8:14.) In February of 2012, shortly after receiving the implant, Plaintiff began to experience severe pelvic pain, vaginal pain, recurrent urinary tract infections, severe pain with intercourse, disabling prudential neuropathy, severe labial and perineal neuropathy, increased urinary frequency, urge incontinence, bowel dysfunction, groin pain, and vaginal wall damage. (ECF No. 111-1 at 6; ECF No. 131-9 at 28:18–30:14, 34:11–21.) Dr. Gregory Hseih performed a mesh revision surgery on March 16, 2012, which removed a portion of the mesh (ECF No. 131-3 at 34:4–35:22; ECF No. 111-1 at 10–11), and after continued complaints from Plaintiff, Dr. Hseih performed another surgery on July 19, 2012 (ECF No. 131-3 at 50:25–53:19). On February 8, 2013, Dr. Ja-Hong Kim surgically removed additional mesh and performed vaginal reconstruction and bladder neck suspension. (ECF No. 131-9 at 35:18–36:2.) Plaintiff's case-specific expert, Dr. Bruce Rosenzweig, opines that Plaintiff will likely experience permanent conditions of mesh erosion, urinary incontinence, recurrent stress urinary incontinence, bladder spasms, overactive bladder, increased urinary frequency and nocturia, pelvic pain, vaginal pain, groin pain, obstructed voiding, recurrent urinary tract infections, dyspareunia and hyspareunia, and that Plaintiff may need further mesh excision procedures. (ECF No. 131-12 at 68–69.)

Dr. Schwartz testified that she had some awareness of risks of vaginal scarring and mesh erosion from the use of surgically implanted mesh products prior to January of 2012, as she was aware of FDA public health notifications

from October of 2008 and December of 2011. (ECF No. 131-5 at 58:10–62:11.) Dr. Schwartz also testified that her knowledge of mesh-related risks has grown over the course of her practice and that she is aware of data from after January of 2012 that has shown increased concern about complications after mesh implantation procedures. (*Id.* at 131:20–132:6.) She testified that before she counseled and performed the surgical procedure on Plaintiff, she did not have the awareness of the increased risks associated with shorter mesh slings that she later came to have. (*Id.* at 132:8–133:1.) She also testified that prior to Plaintiff's surgery, she did not know the percentage of people who would have complications that would not improve over time. (*Id.* at 144:23–145:1.) Dr. Oliver testified that he was not told by Ethicon nor otherwise aware of increased risks associated with laser-cut mesh slings. (ECF No. 131-8 at 99:14–101:15.)

Dr. Schwartz testified that she would have changed her patient consenting process with respect to Plaintiff if she had known of the risks of shorter slings. (*Id.* at 134:16–23.) Dr. Oliver testified that awareness of the increased risks of shorter and laser-cut meshes such as the TVT-Abbrevo would have led him to use an alternative product if available. (ECF No. 131-8 at 102:6–103:6.) Plaintiff also testified that she would not have elected to have the mesh sling implanted if she had known of the true risks. (ECF No. 131-7 at 176:22–178:7.)

II. MOTION FOR SUMMARY JUDGMENT

Following a stipulated dismissal of certain claims (ECF No. 95), Plaintiff brings eight claims: (1) negligence; (2) strict liability failure to warn; (3) strict liability defective product; (4) strict liability design defect; (5) fraud; (6) negligent infliction of emotional distress; (7) gross negligence; and (8) unjust enrichment. Defendants moved for summary judgment on all claims, however in the course of the briefing Defendants agreed to withdraw their summary judgment challenge to Plaintiff's design defect claim. (ECF No. 134 at 6.) Likewise, Plaintiff agreed to dismissal of her defective product and unjust enrichment claims. (ECF No. 131

at 15, 23.)

"The purpose of summary judgment is to avoid unnecessary trials when there is no dispute as to the facts before the court." *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1471 (9th Cir. 1994). Summary judgment is appropriate when the pleadings, the discovery and disclosure materials on file, and any affidavits "show there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). An issue is "genuine" if there is a sufficient evidentiary basis on which a reasonable fact-finder could find for the nonmoving party and a dispute is "material" if it could affect the outcome of the suit under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248–49 (1986). The court must view the facts in the light most favorable to the non-moving party and give it the benefit of all reasonable inferences to be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

The party seeking summary judgment bears the initial burden of informing the court of the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. Once the moving party satisfies Rule 56's requirements, the burden shifts to the non-moving party to "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256. The nonmoving party "may not rely on denials in the pleadings but must produce specific evidence, through affidavits or admissible discovery material, to show that the dispute exists[.]" *Bhan v. NME Hosps., Inc.*, 929 F.2d 1404, 1409 (9th Cir. 1991).

A. FAILURE TO WARN

Under Nevada law, strict liability for failure to warn has the same elements as in other strict products liability cases, namely that the plaintiff must show that: (1) the product had a defect which rendered it unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer, and (3) the defect

caused the plaintiffs injury. *Motor Coach Indus., Inc. v. Khiabani by & through Rigaud*, 137 Nev. 416, 419, 493 P.3d 1007, 1011 (2021). The lack of a warning functions as the relevant "defect." *Id.* The burden of proving causation can be satisfied in failure to warn cases by demonstrating that a different warning would have altered the way the plaintiff used the product or would have prompted the plaintiff to take precautions to avoid the injury. *Id.* (citing *Rivera v. Philip Morris, Inc.*, 125 Nev. 185, 191, 209 P.3d 271, 275 (2009)).

The parties agree that the "learned intermediary doctrine" applies (ECF No. 131 at 9), which means that the adequacy of Defendants' warnings is analyzed with respect to the information provided to Plaintiff's implanting surgeons, namely Dr. Schwartz and Dr. Oliver, not with respect to information provided directly to Plaintiff by Defendants. Defendants argue that Plaintiff's failure to warn claim fails on two grounds: (1) Dr. Schwartz and Dr. Oliver were aware of the risks associated with pelvic mesh products such as the TVT-Abbrevo, which means Defendants cannot be liable since there is no duty to warn of known dangers; and (2) Plaintiff lacks evidence that Dr. Schwartz and Dr. Oliver would have changed their decision to recommend the TVT-Abbrevo had further warnings been provided.

On the former, the Court finds that a genuine issue of fact exists as to whether Dr. Schwartz and Dr. Oliver were provided with warnings sufficient to convey the risks associated with the TVT-Abbrevo. The manufacturer's duty is not merely to provide notice of general dangers, but instead to provide more specific information such as the relative frequency with which serious complications occur. *See Allison v. Merck & Co.*, 110 Nev. 762, 774–75, 878 P.2d 948, 956–57 (1994). Here, although Dr. Schwartz and Dr. Oliver testified in their depositions that they had some prior knowledge of the risks associated with pelvic mesh products, they also testified that they were unaware of the increased risks associated with shorter, laser-cut products such as the TVT-Abbrevo. (ECF No.

131-5 at 132:8–133:1; ECF No. 131-8 at 99:14–101:15.) Dr. Schwartz testified that she was unaware of the percentage of patients who would develop irreversible complications from devices like the TVT-Abbrevo. (ECF No. 131-5 at 144:23–145:1.)

On the latter issue, the Court likewise finds that a genuine issue of fact exists as to whether Dr. Schwartz and Dr. Oliver would have changed their decision to recommend the TVT-Abbrevo to Plaintiff had adequate warnings been provided. Dr. Schwartz testified that she would have changed her patient consenting process if she had known of the risks of shorter slings (ECF No. 131-5 at 134:16–23), and Dr. Oliver testified that awareness of the increased risks of shorter and laser-cut meshes would have led him to use an alternative product if available (ECF No. 131-8 at 102:6–103:6). Defendants' motion for summary judgment is denied with respect to Plaintiff's strict liability failure to warn claim.

B. DUPLICATIVE CLAIMS

Defendants move for summary judgment on Plaintiff's fraud claim as duplicative of Plaintiff's failure to warn claim. Defendants argue that Plaintiff cannot employ a fraud claim as a means to circumvent the learned intermediary doctrine and that Plaintiff cannot identify any particular fraudulent statement that Plaintiff detrimentally relied upon. Plaintiff responds that fraud is a valid claim in the learned intermediary context since Defendants knew of risks and failed to disclose them, causing Plaintiff to detrimentally rely on the statements of the learned intermediary. The Court agrees with Plaintiff that the learned intermediary doctrine does not generally bar fraud claims, however the Court also finds that in this case, Plaintiff does not advance any unique facts or allegations specific to her fraud claim that are not present in the failure to warn claim. Plaintiff's fraud claim is therefore entirely duplicative of her strict liability failure to warn claim and therefore dismissal is appropriate. *See Carter v. Ethicon, Inc.*, 2021 WL 1226531, at *4 (D. Nev. Mar. 31, 2021).

Defendants move for summary judgment on Plaintiff's negligence-based claims—negligence, negligent infliction of emotional distress, and gross negligence—as duplicative of Plaintiff's strict liability claims. In response Plaintiff cites *Forest v. E.I. DuPont de Nemours & Co.*, 791 F. Supp. 1460, 1464 (D. Nev. 1992), in which the Court described "the task of distinguishing between negligence and strict liability" as akin to "count[ing] angels on the heads of pins[,]" but nonetheless noted that the claims may differ as to common law defenses such as contributory negligence and therefore "preserved for trial" the "formal dichotomy between the two causes of action[.]" *Id.* at 1464 n.6. The Court disagrees that formally preserving the separate causes of action for trial is necessary. Introduction of common law defenses to negligence-based claims when those defenses do not apply to the analogous strict liability claims founded on entirely the same allegations would waste judicial resources and confuse the issues. Dismissal of Plaintiff's negligence-based claims is appropriate.

III. MOTIONS TO LIMIT TESTIMONY AND OPINIONS

Defendants bring six motions to limit the testimony or opinions of Plaintiff's experts, namely: (1) Dr. Paul J. Michaels (ECF No. 112); (2) Dr. Med. Uwe Klinge (ECF No. 113); (3) Dr. Jeremy Blaivas (ECF No. 114); (4) Dr. Bruce Rosenzweig (ECF No. 115); (5) John Cary, MA (ECF No. 116); and (6) Scott Guelcher, Ph.D. (ECF No. 117). In response to Defendants' motion, Plaintiff withdrew Dr. Blaivas as an expert (ECF No. 118), therefore Defendants' motion will be denied as moot.

Fed. R. Evid. 702 permits a witness who is qualified as an expert by knowledge, skill, experience, training, or education to testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. As

explained in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), five factors have traditionally been used to determine if the principles and methods utilized by the proposed expert are reliable: (1) whether a theory or technique can be tested; (2) whether it has been subjected to peer review and publication; (3) the known or potential error rate of the theory or technique; (4) whether there are standards controlling the technique's operation; and (5) whether the theory or technique enjoys general acceptance within the relevant scientific community.

A. DR. MICHAELS

Defendants seek to exclude Dr. Michaels' opinions regarding proposed alternative mesh materials and designs that he claims would be safer than the polypropylene TVT-Abbrevo mesh, such as absorbable mesh materials and designs with larger pores. Defendants argue that, although Dr. Michaels cites to several scientific studies discussing, for example, the relative incidence of inflammation and foreign body reactions with polypropylene versus other materials, Dr. Michaels has not and cannot cite to any testing of an alternative mesh product as a treatment for the conditions Plaintiff used the TVT-Abbrevo for, namely stress urinary incontinence and pelvic organ prolapse.

In order for a scientific technique to be reliable, there must be evidence in the record indicating the methodology "can be or has been tested." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1046 (9th Cir. 2014) (citing *Cooper v. Brown*, 510 F.3d 870, 880–81 (9th Cir.2007)). The question is whether an expert's methodology can be "challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability." *Id.* (citing Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendments). Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion. *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010), as amended (Apr.

27, 2010).

The Court agrees with Plaintiff's characterization that the scope of the testing inquiry concerns whether the proposed expert's opinions have been subject to scientific testing in a more general sense and is not limited to whether the proposed expert's opinions have been tested precisely within the application at issue in the case. The precise point at which scientific support becomes too general to bear on the specific case is a matter for the Court to decide in each particular case. Overly narrowing the testing requirement would risk precluding opinions for reasons that would be properly the subject of cross examination and impeachment, and such narrowing of the testing requirement would essentially require studies that are perhaps impossible or infeasible to carry out, especially in the medical context. *See Primiano*, 598 F.3d at 565–66 ("The human body is complex, etiology is often uncertain, and ethical concerns often prevent double-blind studies calculated to establish statistical proof.").

Here, the Court finds that the scientific literature cited by Dr. Michaels for the effects of differing materials and pore sizes is sufficiently related to the issues in Plaintiff's case to be generally admitted. *See Carter v. Johnson & Johnson*, No. 2:20-cv-01232-KJD-VCF, 2022 WL 4589583, at *2–3 (D. Nev. Sept. 28, 2022). As explained in *Carter*, it does not appear that Dr. Michaels intends to opine on what specific material a surgeon should use. (ECF No. 112-1 at 7 (listing summary of opinions).) The Court agrees that opining on what specific material a surgeon should use goes beyond the scope of Dr. Michaels' expert role, however, this does not preclude Dr. Michaels from opining on the likelihood of alternative materials and designs causing, for example, different rates of inflammatory reactions. Defendants' motion is denied.

B. DR. KLINGE

Defendants seek to exclude Dr. Klinge's opinion that an alternative design with less mesh material and larger distance between the mesh fibers, specifically

including Ethicon's Ultrapro mesh (which Defendants point out is a product made to treat hernias), would be safer in a woman's pelvic tissues than the TVT-Abbrevo. Defendants argue that Dr. Klinge's Ultrapro opinion should be excluded as unreliable for lack of testing or scientific literature demonstrating that it is safer than the TVT-Abbrevo. Defendants further assert that Dr. Klinge should not be permitted to support the Ultrapro opinion in his expert report by referencing in his deposition a study—the Okulu *et al.* study—that was not cited in his expert report and also that this study cannot support his Ultrapro opinions because it involved different surgical implantation techniques than were used in Plaintiff's case for the TVT-Abbrevo.

The Court agrees with Defendants that under Fed. R. Civ. P. 26(a)(2)(B)(i) and (ii), Dr. Klinge cannot support the opinions in his expert report with a study not disclosed in the report. Nonetheless, even excluding the Okulu *et al.* study, the Court agrees with Plaintiff that Dr. Klinge's Ultrapro alternative design opinion is supported by scientific literature and should be admitted. Similar to the above reasoning regarding Dr. Michaels, just because there are not studies testing Ultrapro *in vivo* for the precise application at issue does not mean that Dr. Klinge's opinions are not founded on rigorous scientific literature. Rather, as noted in *Carter v. Johnson & Johnson*, No. 2:20-cv-01232-KJD-VCF, 2022 WL 4700570, at *3 (D. Nev. Sept. 30, 2022), Dr. Klinge cites numerous scientific studies to support his opinions regarding mesh weight and pore size. (ECF No. 113-1 at 9–15.) Defendants' motion is granted with respect to the Okulu *et al.* study and denied in all other aspects.

C. DR. ROSENZWEIG

Defendants bring three challenges[1] to Dr. Rosenzweig's expert testimony.

[1] Defendants also challenged as unreliable Dr. Rosenzweig's opinions concerning degradation and the manner in which the mesh in the TVT-Abbrevo was cut, however in reply Defendants withdrew their challenges on these topics. (ECF No. 127 at 3, 5.) Defendants also challenge Dr. Rosenzweig's

First, Defendants assert that Dr. Rosenzweig's supplemental report improperly includes additional opinions based on information available before the close of MDL discovery in contravention of the Court's limitation of the re-opening of discovery to occurrences after the close of the MDL discovery. Second, Defendants argue that Dr. Rosenzweig should be prohibited from testifying that non-mesh surgical procedures, such as those which use biological slings, are safer alternatives to surgeries using mesh products. Third, Defendants argue that Dr. Rosenzweig should be precluded from testifying that a different type of mesh would be a safer alternative.

1. Supplemental Report

As explained in the parties' joint motion to reopen discovery (ECF No. 104), discovery in the MDL case closed on October 25, 2019. The Court granted the parties' joint motion to reopen discovery "for the limited purpose of addressing changes in Plaintiff's damages" and set a deadline for supplemental case-specific expert reports "limited to occurrences after the close of MDL discovery[.]" (ECF No. 108 at 2, 3.) Dr. Rosenzweig submitted a supplemental report dated August 8, 2022. (ECF No. 115-2.)

Defendants' challenge Dr. Rosenzweig's reference to the deposition testimony of Dr. Ja-Hong Kim, which Dr. Rosenzweig cites when discussing his revised opinion that Plaintiff suffers from obturator neuralgia and pudendal neuralgia. Defendants point out that the deposition of Dr. Kim occurred on September 30, 2019, before the close of discovery in the MDL. Thus, Defendants argue that Dr. Rosenzweig cannot rely on Dr. Kim's deposition since that deposition does not fall within the limited scope for which discovery was reopened, namely for post-MDL occurrences. Plaintiff responds that although Dr.

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opinions concerning warnings "for the reasons set forth in Ethicon's concurrently filed summary judgment motion[.]" (ECF No. 115 at 6.) Since the Court denies Defendants' motion for summary judgment and Defendants provide no further argument on this topic, the Court rejects Defendants' challenge to Dr. Rosenzweig's warning opinions.

Kim's deposition occurred during the MDL discovery, the deposition occurred six weeks after the deadline on which Dr. Rosenzweig submitted his original expert report and therefore supplementation is warranted. Defendants reply that the proper procedure would have been for Plaintiff to supplement Dr. Rosenzweig's expert report shortly after Dr. Kim's deposition was taken pursuant to Fed. R. Civ. P. 26.

The Court agrees that Dr. Rosenzweig's use of Dr. Kim's deposition is improper given that it is not a post-MDL occurrence. However, Dr. Rosenzweig's opinions regarding obturator and pudendal neuralgia are not based only on Dr. Kim's deposition testimony but also upon Plaintiff's medical records and Plaintiff's deposition. (ECF No. 115-2 at 16–19.) The Court grants Defendants' motion to preclude Dr. Rosenzweig from referring to Dr. Kim's 2019 deposition and denies Defendants' motion in all other aspects on the subject of Dr. Rosenzweig's supplemental report.

2. Alternative Procedures

Defendants argue that Dr. Rosenzweig should be precluded from offering testimony on alternative procedures that do not utilize a mesh implant, such as the "Burch" surgical procedure which does not require implanting a device, or the use of autologous or allograft slings, which are biological slings that use the patient's own tissues or donor tissues, respectively. Defendants assert that these alternative procedures are not relevant to the issue of whether an alternative design exists for the product at issue, which is a synthetic mesh product. Since the decision to utilize a certain surgical approach over another involves patient-specific medical considerations, Defendants reason that introduction of this evidence would confuse the issues since the central issue in this case is the design of the product for a mesh-based procedure. Plaintiff responds that under Nevada law, an alternative design is not a required element of a strict liability defective design claim, meaning alternative procedures are permissible as

alternatives, and that the jury should be allowed to hear about alternative procedures to contextualize the risks associated with mesh products, especially since Defendants' experts assert that mesh products are the "gold standard" for treating conditions such as stress urinary incontinence.

The Court agrees, following *Carter v. Johnson & Johnson*, 2022 WL 4700567, at *2–3 (D. Nev. Sept. 30, 2022), that alternative procedures are not generally relevant to the issue in this case, which is the design of a mesh product, and that the presence of patient-specific considerations in recommending the use of a mesh over alternative procedures carries the risk of confusing the issues. Therefore, Dr. Rosenzweig will not be permitted in the first instance to opine that alternative procedures are safer alternatives to the TVT-Abbrevo. However, the Court will permit Plaintiffs to rebut any representation by Defendants that mesh products are safer alternatives to non-mesh procedures. Therefore, the Court will permit Plaintiff to provide alternative procedure evidence should Defendants open the door by introducing such evidence themselves.

3. Mesh Type

Defendants argue that Dr. Rosenzweig should be prohibited from opining that a device with lighter weight and greater porosity, such as Defendants' Ultrapro product, would be a safer alternative to the TVT-Abbrevo because Dr. Rosenzweig's expert reports do not contain the specific assertion that Plaintiff's injuries would have been lessened if she had been implanted with such an alternative. Plaintiff responds that: (1) the MDL Court already ruled that Dr. Rosenzweig's opinions about a lighter-weight, larger-pore mesh such as the Ultrapro are admissible; (2) Dr. Rosenzweig does reference lighter-weight, larger-pore mesh such as the Ultrapro in his reports; and (3) Dr. Rosenzweig testified in his deposition that the Ultrapro would have reduced the risk of injury for Plaintiff.

The Court agrees with Plaintiff that Dr. Rosenzweig's report sufficiently discusses a lighter-weight, larger-pore mesh such as the Ultrapro to put

Defendants on notice of Dr. Rosenzweig's opinion. The report states that "Ethicon had lighter weight, larger pore meshes that were less stiff and rigid, and more compliant with patients' tissues that it marketed for use in the pelvis[,]" and the report discusses Ultrapro by name. (ECF No. 124-1 at 41, 67.) Defendants' motion is denied on this point.

D. JOHN CARY

Defendants challenge the introduction of Plaintiff's damages expert, John Cary, who was disclosed by Plaintiff following the Court's limited reopening of discovery to address occurrences after the close of discovery in the MDL. Defendants assert that Mr. Cary's opinions are improper because they are based on the totality of the evidence available, including evidence available before the close of MDL discovery. Plaintiff responds that Mr. Cary's retention as a damages expert arose from the change in Dr. Rosenzweig's opinion that occurred after the close of MDL discovery: Dr. Rosenzweig first opined that Plaintiff's required medical care could range from 6 months to 5 years, then in his supplemental report opined that treatments would likely need to be performed over the remainder of Plaintiff's life, and Plaintiff notes Mr. Cary's opinion that Plaintiff has a life expectancy of an additional 31.8 years. (ECF No. 121 at 11–12.) Plaintiff also points out that she lost her job after the close of MDL discovery and asserts that Mr. Cary's report is responsive to that occurrence.

The parties' joint motion to reopen discovery states that "since the close of discovery in the MDL, Plaintiff has continued to receive medical treatment for her mesh-related injuries and has sustained a change in employment status as a result of the progression of her injuries and job duties. These recent developments could necessitate the need for vocational and/or damages expert(s) limited to occurrences since the close of MDL discovery." (ECF No. 104 at 9.) The Court granted the motion and set forth a deadline for "disclosure of vocational and/or damages expert(s) limited to occurrences after the close of MDL discovery, if

any[.]" (ECF No. 108 at 2.) Although Mr. Cary's report canvasses Plaintiff's medical history prior to the close of MDL discovery, including depositions, Mr. Cary's vocational assessment and life care plan centers on calculating the impact of Plaintiff's injuries on a lifetime basis and on Plaintiff's employment prospects. Although Defendants are correct that Plaintiff could have and did not designate a damages expert during MDL discovery, the permanent nature of Plaintiff's injuries was not known at that time, and, more concretely, the loss of Plaintiff's employment had not occurred. The language of the parties' joint motion and the Court's order put Defendants on reasonable notice that Plaintiff would introduce an expert to address those occurrences. Mr. Cary's analysis must, as a matter of logical necessity, acknowledge and build upon Plaintiff's medical history from the time of MDL discovery.[2] Defendants' motion is denied.

E. DR. GUELCHER

Defendants challenge: (1) the introduction of Dr. Guelcher's alternative procedure opinions, incorporating the arguments from the challenge to Dr. Rosenzweig; and (2) the reliability of Dr. Guelcher's alternative design and degradation opinions. The Court grants Defendants' motion on alternative procedures consistent with § III.C.2, *supra*.

Regarding alternative design, Dr. Guelcher opines that a polyvinylidene fluoride ("PVDF") mesh or a less dense version of a polypropylene mesh would not degrade in the same way as the TVT-Abbrevo. (ECF No. 117-1 at 3.) Defendants assert that Dr. Guelcher is not qualified to give alternative design opinions, that his proposals have not been tested, and that he fails to cite literature that establishes that his proposals are safer. While the MDL Court held that Dr. Guelcher, as a professor of chemical engineering, is not qualified to opine as to

[2] The instant matter is distinct from Defendants' challenge to Dr. Rosenzweig's reliance upon the deposition testimony of Dr. Kim, § III.C.1, *supra*. Dr. Rosenzweig was already disclosed as a case-specific expert on causation, and general updates to causation opinions based on MDL discovery evidence were not within the scope of the limited reopening of discovery.

the medical complications that may be caused by polymer degradation (ECF No. 119-1), it does not appear at this stage that Dr. Guelcher intends to offer opinions as to medical complications. Rather, Dr. Guelcher's testimony will center on the potential for polymer mesh implants to undergo oxidative degradation and what that means as a matter of structural chemistry, which is within Dr. Guelcher's domain of expertise. Furthermore, as Plaintiff points out, Dr. Guelcher has supported his opinions with citations to studies evaluating oxidative degradation of PVDF, Prolene, and other materials in animal implantations. As discussed above with respect to Dr. Michaels, § III.A, *supra*, the testing requirement cannot be so narrow as to require recreation of nearly identical conditions as that which allegedly injured Plaintiff. Here, the testing performed is reliable enough for admissibility and its weaknesses may be properly attacked on cross examination.

Regarding degradation, Defendants assert that an article published by Dr. Guelcher and others, *Talley et al.*, Oxidation and Degradation of Polypropylene Transvaginal Mesh, J. Biomater. Sci., Polymer Ed. (2017) ("Talley"), has been discredited, yet Dr. Guelcher continues to rely upon it for his opinion that polypropylene mesh oxidizes and degrades in the body. Defendants assert that the Talley study authors failed to follow a methodological protocol for actions such as scraping explanted samples, failed to use a sufficiently large sample size or employ control samples, failed to explain their use of a 20% hydrogen peroxide medium to simulate *in vivo* conditions, and came to a speculative conclusion that oxygen found on samples was present due to oxidative degradation and not either naturally present with pristine polypropylene or present as a result of other naturally occurring processes. Defendants also point out that the study authors noted the presence of silicon on nine of the fifteen samples and that silicon is a common laboratory contaminant. Plaintiff responds both by defending the Talley study as a peer-reviewed scientific paper and by pointing out that Dr. Guelcher's opinions on degradation are supported by more than the Talley study.

The Court finds that subject to certain specific exclusions, the Talley study is sufficiently reliable for admissibility and that its weaknesses are proper subjects for cross-examination. The authors discuss the choice to clean the explanted samples by mechanical scraping versus other methods such as ultrasonification and how previous studies likely destroyed their results using those procedures. (ECF No. 119 at 12.) The method chosen here is not so unfounded as to render the experiment inadmissible. Regarding control samples, the authors describe analysis of the *in vitro* samples at zero weeks, which is satisfactory for that part of the experiment. The *in vivo* sample was analyzed both for surface presence of oxygen and for general visual evidence of degradation such as fraying, etc. Although there is not a discussion of surface oxygen in a pristine sample, the observations of general degradation are contextualized against the control samples in the *in vitro* experiment. Therefore the Court will preclude Dr. Guelcher from testifying that the presence of surface oxygen on the *in vivo* sample is evidence of oxidative degradation, but Dr. Guelcher may testify as to the observations of general degradation in the *in vivo* sample. Regarding the oxidative medium for the *in vitro* samples, although Defendants point out that one of the citations used to justify the 20% hydrogen peroxide oxidative medium, the Zhao *et al.* study, used a 10% hydrogen peroxide medium, the Talley study cites more than the Zhao *et al.* study and Defendants do not rebut these citations. (*Id.* at 4.) Finally, the Court agrees with Defendants that the reported carboxylate concentration found in samples 5 and 8 in the supplementary data does not correspond to the spectra shown for those samples (ECF No. 117-11 at Supp. 2–3) and therefore Dr. Guelcher may not offer conclusions which incorporate those samples.

More generally, the Court agrees with Plaintiff that Dr. Guelcher supports his degradation opinions with more than just the Talley study. Defendants' motion is granted in part and denied in part with respect to Dr. Guelcher's

discussion of the Talley study and is denied in all other aspects.

IV. CONCLUSION

Based on the above and in light of the record as a whole, the Court grants Defendants' motion for summary judgment (ECF No. 111) as to Plaintiff's fraud, negligence, negligent infliction of emotional distress, gross negligence, defective product, and unjust enrichment claims and denies Defendants' motion for summary judgment in all other aspects.

The Court further denies Defendants' motion to limit the testimony of Dr. Paul J. Michaels (ECF No. 112).

The Court further grants in part and denies in part Defendants' motion to limit the testimony of Dr. Med. Uwe Klinge (ECF No. 113) as described herein.

The Court further denies as moot Defendants' motion to limit the testimony of Dr. Jeremy Blaivas (ECF No. 114) in light of Plaintiff's withdrawal of Dr. Blaivas as an expert.

The Court further grants in part and denies in part Defendants' motion to limit the opinions of Dr. Bruce Rosenzweig (ECF No. 115) as described herein.

The Court further denies Defendants' motion to limit the opinions of John R. Cary, MA (ECF No. 116).

The Court further grants in part and denies in part Defendants' motion to limit the testimony of Dr. Scott Guelcher, Ph.D (ECF No. 117) as described herein.

DATED THIS 1st day of August 2023.

ANNE R. TRAUM
UNITED STATES DISTRICT JUDGE